CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 10–11–57. Default—destruction.

5566. Digitoxin tablets. (F.D.C. No. 40642. S. No. 68–991 M.)

QUANTITY: 50,000 tablets in a bulk container at Long Island City, N.Y.

SHIPPED: 1–14–57, from Paris, France.

LABEL IN PART: "Digitoxin 0.2 mgm."

RESULTS OF INVESTIGATION: The shipment described above consisted of digitoxin powder, which was subsequently used in preparing the above-described tablets.

Examination showed that the tablets contained not more than 82 percent of the declared amount of digitoxin.

LIBELED: 10–7–57, E. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the declared amount of digitoxin.

DISPOSITION: 11–8–57. Default—destruction.

5567. Soluble saccharin. (F.D.C. No. 40696. S. No. 68–971 M.)

QUANTITY: 1 100-lb. drum at New York, N.Y.

SHIPPED: From Holland.

LIBELED: 10–22–57, S. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for soluble saccharin set forth in the United States Pharmacopeia since the article exceeded the heavy metals limit of 20 parts per million prescribed by the standard.

DISPOSITION: 11–22–57. Default—destruction.

5568. Chorionic gonadotropin. (F.D.C. No. 40929. S. No. 57–847 M.)

QUANTITY: 25 boxes, 2 vials each, at Atlanta, Ga.

SHIPPED: 7–25–57, from Los Angeles, Calif.

LABEL IN PART: "Chorionic Gonadotropin 5,000 I.U. For Preparation of Solution in Intramuscular Injection" and "10 cc. Vial Diluent for Chorionic Gonadotropin."

RESULTS OF INVESTIGATION: Analysis showed that the article contained substantially less than 5,000 I.U. of chorionic gonadotropin potency per vial.

LIBELED: 10–31–57, N. Dist. Ga.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported or was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 5,000 I.U." was false and misleading.

DISPOSITION: 12–9–57. Default—destruction.

5569. Chorionic gonadotropin. (F.D.C. No. 40923. S. No. 67–814 M.)

QUANTITY: 7 boxes, 2 vials each, at Tulsa, Okla.

SHIPPED: 7–15–57, from Los Angeles, Calif.

LABEL IN PART: "10 cc. Vial Diluent for Chorionic Gonadotropin * * * Contains 0.5% Phenol" and "Chorionic Gonadotropin 5,000 I.U. * * * For Intramuscular Injection Only."

RESULTS OF INVESTIGATION: Analysis showed that the article contained substantially less than 5,000 I.U. of chorionic gonadotropin potency per vial.

LIBELED: 11-7-57, N. Dist. Okla.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 5,000 I.U." was false and misleading.

DISPOSITION: 12-2-57. Default—destruction.

5570. Del-Caps. (F.D.C. No. 40851. S. No. 59-057 M.)

QUANTITY: 1 drum containing 21,000 capsules, 4 1,000-capsule btls., 8 500-capsule btls., and 18 100-capsule btls. at Philadelphia, Pa.

SHIPPED: 6-4-57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Drum) "Del-Caps" 15 Timed Disintegration Capsule. Each Capsule Contains: Dextro Amphetamine Sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6-10 hours * * * Delmar Pharmacal Corp."

RESULTS OF INVESTIGATION: The capsules in the btls. had been repackaged by the dealer from the above-mentioned bulk drum.

Examination showed that the article contained the labeled amount of dextro-amphetamine sulfate; that 68 percent of the dextro-amphetamine sulfate ingredient was released within the first 2 hours; and that the entire labeled amount of such ingredient was released within 5 hours.

LIBELED: 10-23-57, E. Dist. Pa.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess, namely, the capsules of the article failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the label of the article contained a false and misleading representation that the dextro-amphetamine sulfate ingredient of the article would be released at a uniform rate over a 6- to 10-hour period.

DISPOSITION: 11-25-57. Default—destruction.

5571. Pyrilamine maleate capsules. (F.D.C. No. 40905. S. No. 68-952 M.)

QUANTITY: 20 ctns. at Woodside, N.Y.

SHIPPED: 6-19-57, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

LABEL IN PART: "1000 Capsules Timcaps Pyrilamine Maleate 75 Mg. Timed Disintegration Capsule Each Capsule Contains 75 Mg. Pyrilamine Maleate Released gradually and equivalent to 3 doses of 25 mg. over a period of approximately 8 hours * * * Control 6668 * * * Distributed by Henry Schein Woodside, L.I., N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article contained the labeled amount of pyrilamine maleate and that it released 86 percent of its pyrilamine maleate content within 2 hours and 94 percent in 6 hours.

LIBELED: 10-29-57, E. Dist. N.Y.